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09/520,130

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Robert Arathoon

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/520,130 | Applicant(s) ARATHOON ET AL. | |
| | Examiner ANNE L. HOLLERAN | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/14/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/22/2009 has been entered.

The amendment filed 4/22/2009 is acknowledged.

The amendment filed 7/14/2009 is acknowledged. Claims 64-77 are pending and examined on the merits.

Claim Rejections Withdrawn:

Claim Rejections - 35 USC § 102

The rejection of claims 54 and 56 under 35 U.S.C. 102(b) as being anticipated by de Kruif-A (de Kruif, J. et al. Journal of Biological Chemistry, 271(13): 7630-7634, 1996; cited in IDS) as evidenced by de Kruif-B (de Kruif, J. et al, J. Mol. Biol., 248: 97-105, 1995; cited in IDS) is moot in view of the cancellation of claims 54-63.

Claim Rejections - 35 USC § 103

The rejection of claims 54, 55, 58-61, and 63 under 35 U.S.C. 103(a) as being obvious over Carter-B (WO 96/27011; published 6 Sep., 1996; cited in IDS) in view of de Kruif-A (de

Art Unit: 1643

Kruif, J. et al. The Journal of Biological Chemistry, 271 (13): 7630-7634, 1996; cited in IDS) and further in view of de Kruif-B (de Kruif, J. et al, J. Mol. Biol., 248: 97-105, 1995; cited in IDS) is moot in view of the cancellation of claims 54-63.

The rejection of claims 54, 56-60 and 63 under 35 U.S.C. 103(a) as being unpatentable over Hu (Hu, S.-z., et al., Cancer Research, 56: 3053-3061, 1996; cited in the IDS) in view of de Kruif-A (supra) and further in view of de Kruif-B (supra) is moot in view of the cancellation of claims 54-63.

Claim Rejections Maintained and New Grounds of Rejection:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1643

Claims 64-77 remain/are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 56-77 of copending Application No. 09/373,403. The rejection is maintained for the reasons of record.

Claims 64-77 remain/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45-82 of US Patent No. 7,183,076. This rejection was originally a provisional rejection over application no. 10/143,437. The rejection is maintained for the reasons of record.

Applicants have requested that the examiner hold these rejections in abeyance until notice of allowable subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 64-77 remain/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is maintained for the reasons of record.

Applicants argue that the previously cited passages (page 22, line 18 to page 23, line 5; as well as Example 4 and Figure 4) provide explicit support for useful light chains that different in

Art Unit: 1643

their amino acid sequence outside the CDR regions, and that a person of ordinary skill in the art would reasonably conclude that the applicants had possession of a bispecific antibody formed from two such useful light chains. This is not found persuasive because the specification fails to provide explicit support for bispecific antibodies having common light chains, where the common light chains are not identical in amino acid sequence to each other. This passage does not describe any species of bispecific or multispecific antibody comprising two light chains that are different in amino acid sequence. With respect to Example 4, the same is true. The teachings of Example 4 provide one with a method of discovering a set of useful light chains to be used individually within a bispecific or multispecific antibody. There is no teaching that two light chains may be chosen from the set and used to make a bispecific or multispecific antibody, and where the two light chains are interchangeable within a bispecific or multispecific antibody. The first sentence of Example 4, on page 95, is the following: "The following example demonstrates preparation of a heteromultimeric bispecific antibody sharing *the same light* chain according to the invention and the ability of that antibody to bind its target antigens." [emphasis added] Therefore, contrary to applicants' assertions there is no support in the specification for claimed multispecific antibodies. The rejection is maintained for the reasons of record.

New Grounds of Rejection:***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1643

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 64, 65, 69, 70, 72 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Tachibana (Tachibana, H., et al. Hum. Antibod. Hybridomas, 4: 42-46, 1993; cited in IDS).

Tachibana teaches a bispecific antibody comprising two different heavy chains and one light chain (see 44, right column – 46, left column). Therefore, Tachibana teaches a multispecific antibody that is within the scope of the claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
/Alana M. Harris, Ph.D./

29 March 2010